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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/267,043	12/12/91	ROON	UD925200

EXAMINER

ELLIS, T

16

ART UNIT	PAPER NUMBER
1812	1812

DATE MAILED:

*D. W. Ellis  
3/23/93*

03/23/93

### NOTICE OF ALLOWABILITY

#### PART I.

- This communication is responsive to application filed 12/12/91.
- All the claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.
- The allowed claims are 12, 20, 21, 23, 28, 35, 42-44, 46, and 143-148.
- The drawings filed on \_\_\_\_\_ are acceptable.
- Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has [ ] been received. [ ] not been received. [ ] been filed in parent application Serial No. \_\_\_\_\_, filed on \_\_\_\_\_.
- Note the attached Examiner's Amendment.
- Note the attached Examiner Interview Summary Record, PTO-413.
- Note the attached Examiner's Statement of Reasons for Allowance.
- Note the attached NOTICE OF REFERENCES CITED, PTO-892.
- Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449.

#### PART II.

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

- Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
- APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
  - Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No. \_\_\_\_\_ CORRECTION IS REQUIRED.
  - The proposed drawing correction filed on \_\_\_\_\_ has been approved by the examiner. CORRECTION IS REQUIRED.
  - Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.
  - Formal drawings are now REQUIRED.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

#### Attachments:

- Examiner's Amendment
- Examiner Interview Summary Record, PTO- 413
- Reasons for Allowance
- Notice of References Cited, PTO-892
- Information Disclosure Citation, PTO-1449

- Notice of Informal Application, PTO-152
- Notice re Patent Drawings, PTO-948
- Listing of Bonded Draftsmen
- Other

*D. J. Ellis*  
JOAN ELLIS  
PRIMARY EXAMINER  
GROUP 180

USPO

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Mr. N. Hanson on March 19, 1993.

Please amend the claims as follows:

Claim 12,

line 1, delete, "The" and "of claim 1, wherein said",  
insert, "An" before "isolated",  
insert, "which" after "molecule",  
line 2, delete, "molecule", "a" and "or is complementary to a",  
insert, "the" before "MAGE",  
insert, "1 tumor rejection" after "MAGE",  
insert, "precursor as set forth in SEQ. ID. NO. 8." after  
"antigen",  
line 3, delete in its entirety.

Claim 20,

line 1, delete, "16",  
insert, "12" after "claim",  
line 2, delete, "DNA",  
insert, "nucleic acid molecule" before "is",  
insert, "a" after "is",  
insert, "which comprises nucleotides 3881 to 4711 of SEQ. ID.  
NO. 8" after "cDNA".

Claim 21,

line 1, delete, "The", "nucleic acid", and "of claim 18, wherein said",  
insert, "An" before "isolated",  
insert, "mRNA" after "isolated",  
insert, "which is complementary to the nucleic acid molecule of  
claim 12" after "molecule",  
line 2, delete in its entirety.

Claim 23,

line 1, delete, "The" and "of claim 15, wherein said",  
insert, "An" before "isolated",  
insert, "which hybridizes to the" after "molecule",  
line 2, delete, "molecule which hybridizes to a molecule which codes for  
a",  
insert, "the" before "MAGE",  
insert, "1 nucleic acid molecule of claim 12" after "MAGE",  
line 3, delete, "antigen",  
insert, "and which codes for a tumor rejection antigen  
precursor" after "conditions".

Claim 28,

line 1, delete, "Biologically pure culture of a" and "line"  
insert, "A host" before "cell",  
line 2, delete, "sequence",  
insert, "molecule" after "acid".

Claim 35,

line 1, delete, "Biologically pure", "line", "34", and "said tumor  
rejection",  
insert, "The host" before "cell",

insert, "148, wherein" after "claim",  
line 2, delete, "antigen precursor is mage-1 and said isolated DNA",  
insert, "MAGE 1" after "and",  
insert, "the", before "nucleic",  
line 3, insert, "as follows" after "sequence",  
lines 4 and the final line, delete "1 10 1 20 1 30 1 40 1 50 1  
60".

Claim 42,

line 1, delete "biologically pure culture" and "27",  
insert "host cell" after "The",  
insert "28" after "claim",  
insert "host cell" after "said",  
line 2, delete, "culture" and "non-proliferative",  
insert, "a mammalian cell".

Claim 43,

line 1, delete, "biologically pure culture" and "27",  
insert, "host cell" after "The",  
insert, "42" after "claim".

Claim 44,

line 1, delete, "Expression" and "useful in transfecting a cell",  
insert, "An expression" before "vector",  
line 2, delete, "2",  
insert, "12" after "claim".

Claim 46,

line 1, delete, "Expression" and "a",  
insert, "The expression" before "vector",  
line 2, delete, "differential",  
insert, " an inducible" before "promoter".

Add the following new claims.

143. An expression vector comprising the isolated nucleic acid molecule of claim 20 operably linked to a promoter.

144. An expression vector comprising the isolated nucleic acid molecule of claim 42 operably linked to a promoter.

145. The expression vector of claim 143, wherein said promoter is an inducible promoter.

146. The expression vector of claim 144, wherein said promoter is an inducible promoter.

147. A host cell line transfected with the nucleic acid molecule of claim 20.

148. A host cell line transfected with the nucleic acid molecule of claim 20.

Cancel claims 1-11, 13-19, 22, 24-<sup>34</sup>~~34~~, 36-41, 45, and 47-142.

The following is an Examiner's Statement of Reasons for Allowance:

In response to the following restriction requirement, applicants agreed to prosecute only those claims directed to the nucleic acid molecule encoding the

MAGE 1 tumor rejection antigen precursor, host cells transfected with said nucleic acid molecule, and expression vectors comprising the MAGE 1 sequence. After extensive searching, the nucleotide sequence encoding MAGE 1 was found to be both novel and non-obvious over the prior art.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-24, 27-29, 33-35, and 42-51, drawn to a nucleic acid a transfected cell line and a vector, classified in Class 435, subclass 240.2.

II. Claims 36-41, 52-57 and 129-135, drawn to cell lines transfected with both a TRAP gene and a cytokine or MHC molecule, methods of making transfected cells, and vectors for the transfection, classified in Class 435, subclass 240.2.

III. Claims 58-70, drawn to antigens and antigen precursors, classified in Class 530, subclass 350.

IV. Claims 71-78, drawn to vaccines, classified in Class 424, subclass 88.

V. Claim 79, drawn to an isolated polypeptide, classified in Class 530, subclass 350.

VI. Claims 80-87, 136, and 138-139, drawn to a pharmaceutical composition comprising a cell line and a method of treating cancer with an antigen-expressing a cell line, classified in Class 424, subclass 93U.

VII. Claims 88-105, drawn to an antibody, classified in Class 530, subclass 388.8.

VIII. Claims 106-117 and 140-142, drawn to a detection method, classified in Class 435, subclass 7.23.

IX. Claims 118-128, drawn to treatment methods, classified in Class 424, subclass 93A.

X. Claim 137, drawn to a therapeutic method of using an antibody wherein said antibody is coupled to an anticancer agent, classified in Class 424, subclass 85.91.

XI. Claim 13, drawn to a nucleic acid encoding mage 2, classified in Class 536, subclass 27.

XII. Claim 96, drawn to an antibody which binds to mage 2, classified in Class 530, subclass 388.8.

XIII. Claim 13, drawn to a nucleic acid encoding mage 3, classified in Class 536, subclass 27.

XIV. Claim 96, drawn to an antibody which binds to mage 3, classified in Class 530, subclass 388.8.

XV. Claim 13, drawn to a nucleic acid encoding mage 4, classified in Class 536, subclass 27.

XVI. Claim 96, drawn to an antibody which binds to mage 4, classified in Class 530, subclass 388.8.

XVII. Claim 13, drawn to a nucleic acid encoding mage 5, classified in Class 536, subclass 27.

XVIII. Claim 96, drawn to an antibody which binds to mage 5, classified in Class 530, subclass 388.8.

XIX. Claim 13, drawn to a nucleic acid encoding mage 6, classified in Class 536, subclass 27.

XX. Claim 96, drawn to an antibody which binds to mage 6, classified in Class 530, subclass 388.8.

XXI. Claim 13, drawn to a nucleic acid encoding mage 7, classified in Class 536, subclass 27.

XXII. Claim 96, drawn to an antibody which binds to mage 7, classified in Class 530, subclass 388.8.

XXIII. Claims 25, 26, 30-32, drawn to a nucleic acid sequence encoding P815 and a transfected cell line, classified in Class 435, subclass 240.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the product can be made by a materially different process such as the Merrifield chemical synthesis technique.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as a reagent in a diagnostic assay.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as the expression and production of the mage 1 antigen for use in a diagnostic assay.

Inventions III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as a reagent in a diagnostic assay.

Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product as claimed can be used in a materially different

process such as the expression and production of the mage 1 antigen for use in the production of antibodies.

Inventions I and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as a detection assay for cancer.

Inventions VII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as use in a detection or diagnostic assay.

Inventions II, V, XI, XIII, XV, XVII, XIX, XXI, and XXIII are patentably distinct products. They are direct to nucleotide sequences, transfected cell lines and polypeptides which differ in structure and function from the each other and from inventions I and III, supra.

Inventions XI, XIII, XV, XVII, XIX, XXI and XII, XIV, XVI, XVIII, XX, XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as the expression and production of the MAGE antigens for diagnostic or detection assays.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. N. Hanson on March 19, 1993 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-24, 27-29, 33-35, and 42-51. Affirmation of this election must be made by applicant in responding to this Office action. Claims 25, 26, 30-32, 36-41, and 52-142 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably accompany the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

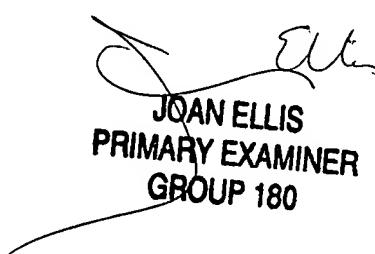
Serial No. 07/807,043  
Art Unit 1813

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Ellis whose telephone number is (703) 308-3990.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Ellis, Ph.D.  
March 19, 1993

  
JOAN ELLIS  
PRIMARY EXAMINER  
GROUP 180



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

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18N1

**NOTICE OF ALLOWANCE  
AND ISSUE FEE DUE**

- Note attached communication from the Examiner  
 This notice is issued in view of applicant's communication filed \_\_\_\_\_

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
07/807,043	12/12/91	016	ELLIS, J	1813 03/23/93
First Named Applicant	BOON, THIERRY			

TITLE OF INVENTION THE NUCLEOTIDE SEQUENCE ENCODING THE TUMOR REJECTION ANTIGEN PRECURSOR MAGE-1 (AS AMENDED)

	ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEES DUE	DATE DUE
1	LUD25333	435-240.200	L60	UTILITY	YES	\$585.00	06/23/93

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT.  
PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

**HOW TO RESPOND TO THIS NOTICE:**

I. Review the SMALL ENTITY Status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the Status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the Status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by a charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, Part C of this notice should also be completed and returned.

III. All communications regarding this application must give series code (or filing date), serial number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees.**